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and Evofem Biosciences Operations, Inc.

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EVOFEM BIOSCIENCES, INC., EVOFEM, INC., and EVOFEM BIOSCIENCES OPERATIONS, INC., Plaintiffs, v. PADAGIS ISRAEL PHARMACEUTICALS LTD., PADAGIS US LLC, and PADAGIS LLC, Defendants.	Civil Action No. 2:23-3003

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Evofem Biosciences, Inc., Evofem, Inc., and Evofem Biosciences Operations, Inc. (collectively, "Evofem"), by their attorneys, file this Complaint against Defendants Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively, "Padagis"), and allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., which arises out of the submission by Padagis of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA")

seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of the vaginal gel product currently marketed under the trade name PHEXXI® prior to the expiration of U.S. Patent Nos. 10,568,855 ("the '855 patent"), 11,337,989 ("the '989 patent"), and 11,439,610 ("the '610 patent") (collectively, "the Patents-in-Suit").

PARTIES

2. Plaintiff Evofem Biosciences, Inc. is a corporation organized and existing under the laws of Delaware, having a mailing address at 7770 Regents Rd, Suite 113-618, San Diego, California 92122.

3. Plaintiff Evofem, Inc. is a corporation organized and existing under the laws of Delaware, having a mailing address at 7770 Regents Rd, Suite 113-618, San Diego, California 92122.

4. Plaintiff Evofem Biosciences Operations, Inc. is a corporation organized and existing under the laws of Delaware, having a mailing address at 7770 Regents Rd, Suite 113-618, San Diego, California 92122.

5. On information and belief, Defendant Padagis Israel Pharmaceuticals Ltd. ("Padagis Israel") is a corporation organized and existing under the laws of Israel, having a place of business at 1 Rakefet St., Shoham, 608500, Israel.

6. On information and belief, Defendant Padagis US LLC ("Padagis US") is a limited liability company organized and existing under the laws of Delaware, having a place of business at 1251 Lincoln Road, Allegan, Michigan 49010.

7. On information and belief, Defendant Padagis LLC ("Padagis LLC") is a limited liability company organized and existing under the laws of Delaware, having a place of business at 1251 Lincoln Road, Allegan, Michigan 49010.

8. On information and belief, Padagis Israel is a wholly owned subsidiary of Padagis LLC.

9. On information and belief, Padagis US is a wholly owned subsidiary of Padagis LLC.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. As set forth in Paragraphs 12-15 below, this Court has personal jurisdiction over Padagis Israel by virtue of, among other things, its systematic and continuous contacts with the State of New Jersey.

12. On information and belief, Padagis Israel is in the business of, among other things, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. On information and belief, Padagis Israel directly or indirectly develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for the Padagis ANDA Product (as defined below).

13. On information and belief, Padagis Israel purposefully has conducted and continues to conduct business in this judicial district.

14. On information and belief, Padagis Israel has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Bausch Health Ireland Ltd. et al. v. Padagis Israel Pharms. Ltd. et al.*, No. 2:22-cv-04248 (D.N.J.).

15. Alternatively, if the exercise of personal jurisdiction over Padagis Israel in this Court is not held to be proper, then, on information and belief, this Court has personal jurisdiction over Padagis Israel pursuant to Federal Rule of Civil Procedure 4(k)(2) because Padagis Israel has extensive contacts with the United States, including but not limited to the above-described commercial contact, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Padagis Israel is consistent with the laws of the United States and the United States Constitution.

16. As set forth in Paragraphs 17-21 below, this Court has personal jurisdiction over Padagis US by virtue of, among other things, its systematic and continuous contacts with the State of New Jersey.

17. On information and belief, Padagis US is in the business of, among other things, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. On information and belief, Padagis US directly or indirectly develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for the Padagis ANDA Product (as defined below).

18. On information and belief, Padagis US purposefully has conducted and continues to conduct business in this judicial district.

19. On information and belief, Padagis US is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Entity ID No. 0600473527.

20. On information and belief, Padagis US is registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under the registration number 5006088.

21. On information and belief, Padagis US has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *GW Research Ltd. v. Teva Pharms., Inc. et al.*, No. 2:23-cv-00018 (D.N.J.); *Bausch Health Ireland Ltd. et al. v. Padagis Israel Pharms. Ltd. et al.*, No. 2:22-cv-4248 (D.N.J.).

22. As set forth in Paragraphs 23-25 below, this Court has personal jurisdiction over Padagis LLC by virtue of, among other things, its systematic and continuous contacts with the State of New Jersey.

23. On information and belief, Padagis LLC is in the business of, among other things, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. On information and belief, Padagis LLC directly or indirectly develops, manufactures, markets, and/or sells generic drug products throughout the United States and in this judicial district through its subsidiaries, and this judicial district is a likely destination for the Padagis ANDA Product (as defined below).

24. On information and belief, Padagis LLC purposefully has conducted and continues to conduct business in this judicial district, at least through its wholly owned subsidiaries Padagis Israel and Padagis US.

25. On information and belief, Padagis LLC has previously submitted to the jurisdiction of this Court. *See, e.g.*, *Bausch Health Ireland Ltd. et al. v. Padagis Israel Pharms. Ltd. et al.*, No. 2:22-cv-04248 (D.N.J.).

26. On information and belief, Padagis Israel, Padagis US, and Padagis LLC hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products. On information and belief, Padagis LLC exercises control over Padagis Israel and Padagis US.

27. On information and belief, Padagis has taken the significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Padagis ANDA Product (as defined below), that will be purposefully directed at New Jersey and elsewhere. The filing of the Padagis ANDA (as defined below) constitutes a formal act that reliably indicates plans to engage in the manufacturing, marketing, selling, and distributing of the Padagis ANDA Product (as defined below).

28. On information and belief, Padagis intends to direct sales of the Padagis ANDA Product (as defined below) into New Jersey, among other places, once it has received final FDA approval to market it.

29. On information and belief, Padagis will engage in marketing of the Padagis ANDA Product (as defined below) in New Jersey upon approval of the Padagis ANDA (as defined below).

30. In addition, jurisdiction is proper in this district with respect to Padagis Israel, Padagis US, and Padagis LLC because all three have agreed in writing not to contest personal jurisdiction in the United States District Court for the District of New Jersey for purposes of this action, and thus have consented to personal jurisdiction in this district for the purposes of this action.

31. On information and belief, venue is proper in this district under 28 U.S.C. §§ 1391 and 1400(b).

32. Venue is proper in this judicial district as to Padagis Israel, because Padagis Israel is a foreign corporation, and this judicial district has personal jurisdiction over Padagis Israel.

33. Venue is proper as to Padagis Israel, Padagis US, and Padagis LLC because each has previously consented to venue in this judicial district.

34. In addition, venue is proper in this district with respect to Padagis Israel, Padagis US, and Padagis LLC because all three have agreed in writing not to contest venue in this district for the purposes of this action, and thus have consented to venue in this district for the purposes of this action.

PATENTS-IN-SUIT

35. On February 25, 2020, the '855 patent entitled "Compositions and Methods for Enhancing the Efficacy of Contraceptive Microbicides" was duly and legally issued. A true and correct copy of the '855 patent is attached to this Complaint as Exhibit A.

36. The FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists the expiration of the '855 Patent as March 15, 2033.

37. Evofem, Inc. is the assignee of the '855 patent.

38. On May 24, 2022, the '989 patent entitled "Compositions and Methods for Inhibiting Inflammation and Diseases Using an Alginic Acid-Based Antimicrobial Compound" was duly and legally issued. A true and correct copy of the '989 patent is attached to this Complaint as Exhibit B.

39. The Orange Book lists the expiration of the '989 Patent as March 15, 2033.

40. Evofem, Inc. is the assignee of the '989 patent.

41. On September 13, 2022, the '610 patent entitled "Compositions and Methods for Enhancing the Efficacy of Contraceptive Microbicides" was duly and legally issued. A true and correct copy of the '610 patent is attached to this Complaint as Exhibit C.

42. The Orange Book lists the expiration of the '610 Patent as March 15, 2033.

43. Evofem, Inc. is the assignee of the '610 patent.

ACTS GIVING RISE TO THE ACTION

44. Evofem, Inc. holds the approved New Drug Application ("NDA") No. 208352 for the vaginal gel product currently marketed under the trade name PHEXXI®.

45. PHEXXI® is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

46. Pursuant to 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the Patents-in-Suit are listed in the Orange Book for PHEXXI®, and were so listed at the time the Padagis ANDA (defined below) was submitted to the FDA.

47. Padagis notified Evofem by letter dated April 18, 2023 ("the Notice Letter") that it had submitted to the FDA ANDA No. 217960 ("the Padagis ANDA"), seeking approval from the FDA "to engage in the commercial manufacture, use, and/or sale of lactic acid, citric acid, and potassium bitartrate vaginal gel" ("the Padagis ANDA Product") under 21 U.S.C. § 355(j) prior to the expiration of the Patents-in-Suit.

48. The Notice Letter indicated that the Padagis ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the Patents-in-Suit ("Paragraph IV Certification").

49. The Notice Letter does not allege non-infringement for any claim of the Patents-in-Suit.

50. By not identifying non-infringement defenses for any claim of the Patents-in-Suit in the Notice Letter, Padagis admitted that the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product meets all limitations of all claims in the Patents-in-Suit.

51. The Notice Letter does not allege invalidity under 35 U.S.C. §§ 101 or 102, or unenforceability for any claim of the Patents-in-Suit.

52. By not identifying invalidity defenses under 35 U.S.C. §§ 101 or 102, or unenforceability defenses for the Patents-in-Suit in the Notice Letter, Padagis admitted that the claims of the Patents-in-Suit are not invalid under 35 U.S.C. §§ 101 and 102, and are enforceable.

53. Evofem is commencing this action within 45 days of receiving the Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I: INFRINGEMENT OF THE '855 PATENT

54. Evofem realleges and incorporates by reference the allegations contained in the preceding paragraphs.

55. The Notice Letter does not allege that the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product will not infringe any claim of the '855 patent.

56. The Notice Letter does not identify any limitation of the claims of the '855 patent that is absent from the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product.

57. Pursuant to 35 U.S.C. § 271(e)(2)(A), Padagis has committed an act of infringement of the '855 patent by submitting the Padagis ANDA to obtain approval to engage in the commercial

manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product in the United States prior to the expiration of the '855 patent.

58. Padagis's actions, including but not limited to, the development of the Padagis ANDA Product, and the filing of the Padagis ANDA with the Paragraph IV Certification, reliably indicate that Padagis has made and will continue to make substantial preparation in the United States, including in the District of New Jersey, to manufacture, sell, offer to sell, and/or import the Padagis ANDA Product, giving rise to an actual case or controversy between the parties over whether Padagis's future manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to the expiration of the '855 patent will constitute infringement of the '855 patent.

59. On information and belief, Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to the expiration of the '855 patent would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '855 patent.

60. On information and belief, the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '855 patent.

61. On information and belief, Padagis intends to, and will, actively induce infringement of at least one of the claims of the '855 patent after approval of the Padagis ANDA.

62. On information and belief, Padagis knows that the Padagis ANDA Product and its proposed labeling are especially made or adapted for use in infringing at least one of the claims of the '855 patent and that the Padagis ANDA Product and its proposed labeling is not suitable for substantial non-infringing use.

63. On information and belief, Padagis intends to, and will, contribute to infringement of at least one of the claims of the '855 patent after approval of the Padagis ANDA.

64. The foregoing actions by Padagis constitute and/or will constitute infringement of at least one of the claims of the '855 patent, active inducement of infringement of at least one of the claims of the '855 patent, and contribution to the infringement by others of at least one of the claims of the '855 patent.

65. On information and belief, Padagis has acted with full knowledge of the '855 patent and without a reasonable basis for believing that it would not be liable for infringing the '855 patent, actively inducing infringement of the '855 patent, and contributing to the infringement by others of the '855 patent.

66. The commercial manufacture, importation, use, sale, or offer for sale of the Padagis ANDA Product in violation of Evofem's patent rights will cause harm to Evofem for which damages are inadequate.

67. Unless Padagis is enjoined from infringing the '855 patent, Evofem will suffer substantial and irreparable harm for which there is no adequate remedy at law.

68. Evofem is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of the Padagis ANDA be a date that is not earlier than the expiration date of the '855 patent.

COUNT II: INFRINGEMENT OF THE '989 PATENT

69. Evofem realleges and incorporates by reference the allegations contained in the preceding paragraphs.

70. The Notice Letter does not allege that the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product will not infringe any claim of the '989 patent.

71. The Notice Letter does not identify any limitation of the claims of the '989 patent that is absent from the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product.

72. Pursuant to 35 U.S.C. § 271(e)(2)(A), Padagis has committed an act of infringement of the '989 patent by submitting the Padagis ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product in the United States prior to the expiration of the '989 patent.

73. Padagis's actions, including but not limited to, the development of the Padagis ANDA Product, and the filing of the Padagis ANDA with the Paragraph IV Certification, reliably indicate that Padagis has made and will continue to make substantial preparation in the United States, including in the District of New Jersey, to manufacture, sell, offer to sell, and/or import the Padagis ANDA Product, giving rise to an actual case or controversy between the parties over whether Padagis's future manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to the expiration of the '989 patent will constitute infringement of the '989 patent.

74. On information and belief, Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to the expiration of the '989 patent would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '989 patent.

75. On information and belief, the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '989 patent.

76. On information and belief, Padagis intends to, and will, actively induce infringement of at least one of the claims of the '989 patent after approval of the Padagis ANDA.

77. On information and belief, Padagis knows that the Padagis ANDA Product and its proposed labeling are especially made or adapted for use in infringing at least one of the claims of the '989 patent and that the Padagis ANDA Product and its proposed labeling is not suitable for substantial non-infringing use.

78. On information and belief, Padagis intends to, and will, contribute to infringement of at least one of the claims of the '989 patent after approval of the Padagis ANDA.

79. The foregoing actions by Padagis constitute and/or will constitute infringement of at least one of the claims of the '989 patent, active inducement of infringement of at least one of the claims of the '989 patent, and contribution to the infringement by others of at least one of the claims of the '989 patent.

80. On information and belief, Padagis has acted with full knowledge of the '989 patent and without a reasonable basis for believing that it would not be liable for infringing the '989 patent, actively inducing infringement of the '989 patent, and contributing to the infringement by others of the '989 patent.

81. The commercial manufacture, importation, use, sale, or offer for sale of the Padagis ANDA Product in violation of Evofem's patent rights will cause harm to Evofem for which damages are inadequate.

82. Unless Padagis is enjoined from infringing the '989 patent, Evofem will suffer substantial and irreparable harm for which there is no adequate remedy at law.

83. Evofem is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of the Padagis ANDA be a date that is not earlier than the expiration date of the '989 patent.

COUNT III: INFRINGEMENT OF THE '610 PATENT

84. Evofem realleges and incorporates by reference the allegations contained in the preceding paragraphs.

85. The Notice Letter does not allege that the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product will not infringe any claim of the '610 patent.

86. The Notice Letter does not identify any limitation of the claims of the '610 patent that is absent from the Padagis ANDA Product and/or the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product.

87. Pursuant to 35 U.S.C. § 271(e)(2)(A), Padagis has committed an act of infringement of the '610 patent by submitting the Padagis ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product in the United States prior to the expiration of the '610 patent.

88. Padagis's actions, including but not limited to, the development of the Padagis ANDA Product, and the filing of the Padagis ANDA with the Paragraph IV Certification, reliably indicate that Padagis has made and will continue to make substantial preparation in the United States, including in the District of New Jersey, to manufacture, sell, offer to sell, and/or import the Padagis ANDA Product, giving rise to an actual case or controversy between the parties over

whether Padagis's future manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to the expiration of the '610 patent will constitute infringement of the '610 patent.

89. On information and belief, Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to the expiration of the '610 patent would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '610 patent.

90. On information and belief, the use of the Padagis ANDA Product in accordance with and as directed by Padagis's proposed labeling for that product would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '610 patent.

91. On information and belief, Padagis intends to, and will, actively induce infringement of at least one of the claims of the '610 patent after approval of the Padagis ANDA.

92. On information and belief, Padagis knows that the Padagis ANDA Product and its proposed labeling are especially made or adapted for use in infringing at least one of the claims of the '610 patent and that the Padagis ANDA Product and its proposed labeling is not suitable for substantial non-infringing use.

93. On information and belief, Padagis intends to, and will, contribute to infringement of at least one of the claims of the '610 patent after approval of the Padagis ANDA.

94. The foregoing actions by Padagis constitute and/or will constitute infringement of at least one of the claims of the '610 patent, active inducement of infringement of at least one of the claims of the '610 patent, and contribution to the infringement by others of at least one of the claims of the '610 patent.

95. On information and belief, Padagis has acted with full knowledge of the '610 patent and without a reasonable basis for believing that it would not be liable for infringing the '610 patent, actively inducing infringement of the '610 patent, and contributing to the infringement by others of the '610 patent.

96. The commercial manufacture, importation, use, sale, or offer for sale of the Padagis ANDA Product in violation of Evofem's patent rights will cause harm to Evofem for which damages are inadequate.

97. Unless Padagis is enjoined from infringing the '610 patent, Evofem will suffer substantial and irreparable harm for which there is no adequate remedy at law.

98. Evofem is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of the Padagis ANDA be a date that is not earlier than the expiration date of the '610 patent.

PRAYER FOR RELIEF

WHEREFORE, Evofem prays that this Court grant the following relief:

A. A judgment that each of the Patents-in-Suit has been infringed under 35 U.S.C. § 271(e)(2) by Padagis's submission to the FDA of the Padagis ANDA;

B. A judgment declaring that Padagis's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Padagis ANDA Product prior to the expiration of the Patents-in-Suit, would infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

C. A judgment that the Patents-in-Suit are valid and enforceable;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval of the Padagis ANDA shall not be earlier than the expiration of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

E. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) enjoining Padagis, its affiliates, its subsidiaries, and each of its officers, agents, servants, employees, and attorneys, and all persons acting in privity or concert with them, from making, using, selling, offering to sell, marketing, distributing, or importing the Padagis ANDA Product prior to the expiration of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

F. Damages or other monetary relief pursuant to 35 U.S.C. § 271(e)(4)(C), including costs, fees, pre-judgement interest, and post-judgment interest to Evofem if Padagis commercially manufactures, uses, offers to sell, sells, or imports the Padagis ANDA Product prior to the expiration of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

G. An order pursuant to this Court's equitable power that the effective date of any final approval of the Padagis ANDA shall be a date that is not earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

H. A declaration that this is an exceptional case and that Evofem is entitled to attorneys' fees pursuant to 35 U.S.C. § 285;

I. An award of Evofem's costs and expenses in this action; and

J. Such further and other relief as this Court may deem just and proper.

Dated: June 1, 2023

Respectfully submitted,

/s/ *Charles H. Chevalier*

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